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(H)

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ARTY. DOCKET NO.
09/223,957	12/31/98	DALE R	0119-0004

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EXAMINER

KUNZ, G

ART UNIT PAPER NUMBER

1623

2

DATE MAILED: 03/17/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12-31-98

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

09/223957

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's on prior art admissions on page 2, first paragraph; page 12, lines 1 - 14; and page 14, last paragraph.

Claims 1 - 19 are directed to a method for desalting nucleic acids comprising (1) binding said nucleic acid to a highly hydrophobic column (polystyrene/divinylbenzene); (2) washing with an unbuffered aqueous solution, and 3) eluting with an organic solvent (acetonitrile, n-propanol, isopropanol, methanol). Claim 20 is directed to a method for exchanging the cationic counterion of nucleic acids using the same method as above except the elution is achieved with the preferred counterion instead of an organic solvent.

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The applicant acknowledges on page 2, first paragraph, that the prior art uses reverse phase capture for desalting oligonucleotides by binding said oligonucleotide to a reverse phase liquid chromatography column in the presence of an aqueous salt solution. The applicant indicates that the problem with "Current practice of this technique is limited by the relatively weak absorption of the oligonucleotide by any reverse-phase solid phase." Because of this weak absorption, the oligonucleotide begins to leach off the column as the salt concentration begins to drop below that of the initial sample solution. (lines 3 - 6). In summary, the applicant states that the prior art simply was not using a reverse phase material sufficiently hydrophobic to firmly bind oligonucleotides so they would not leach off in either low salt or in water. Next, the applicant teaches that any number of commercially reverse phase resins are sufficiently hydrophobic to prevent such leaching. These products include DYNAMAX-300A, Pure-DNA-reverse phase columns (1989) [page 12, lines 3 - 4) and Hamilton PRP-1 organic reverse phase column (page 14, lines 3 - 4 from bottom of page). However, implicit in the name "Pure-DNA-reverse phase columns" is the teaching that this column material can and should be used to bind and purify DNA! Therefore, applicant is only selecting a reverse phase material, already taught by supplier to bind DNA, to replace less hydrophobic reverse phase products. The concept of rapid desalting an organic compound on the classical Waters SepPak<sup>R</sup> has been around for over twenty years. And as applicant admits, this same concept has also been used to desalt nucleic acids for quite some time. Applicant has simply used a more hydrophobic material. However, since the art already taught the use of one of these commercially

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available resins ("Pure-DNA-reverse phase columns) to bind, purify, and elute DNA, there can be no inventive step in using this same material to desalt nucleic acid. Therefore, it would have been obvious to the person of ordinary skill in the art at the time of the invention to have used a highly hydrophobic reverse phase resin, taught to be useful for purifying DNA, in the normal desalting procedure. The use of traditional organic solvents to elute said tightly bound DNA is also a conventional principle of reverse phase chromatography. Finally, the exchange of nucleic acid counter salts (claim 20) would have also been obvious by eluting with a high concentration of the counter cation. While applicant has developed a protocol that is an optimal desalting procedure, the principles, materials, and motivation were already in the possession of the public and cannot be deemed non-obvious. The fact that a claimed method is more effective than anticipated is not persuasive of unobviousness where what is claimed would flow naturally from the teachings of the prior art. *In re Adams et al.* (CCPA 1960) 284 F2d 525, 128 USPQ 116; *In re Libby* (CCPA 1958) 255 F2d 412, 118 USPQ 94; *In re Crockett et al.* (1960) 279 F2d 274, 126 USPQ 186; *In re Liesner* (CCPA 1947) 162 F2d 224, 74 USPQ 104; *In re Olsen* (CCPA 1944) 146 F2d 501, 64 USPQ 180.

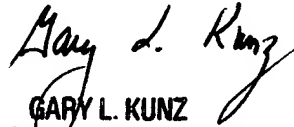
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kunz, whose telephone number is (703) 308-4623. The examiner can normally be reached on Tuesday through Friday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marion Knode, can be reached on (703) 308-4311. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
GARY L. KUNZ  
PRIMARY EXAMINER  
GROUP 1200